REMARKS

Status of Claims and Amendment

Claims 1, 4, 5, 7-10, 12 and 18 are amended. Claims 2, 3, 6, 11-15, 17, 20, 23-26, 29, 31-36, and 38 have been canceled. New claims 41 and 42 are added. Claims 16, 19-22, 27-28, 30, 36-37, and 39-40 are withdrawn as being directed to non-elected inventions. Claims 1, 4, 5, 7-10, 18, 41, and 42 are all the pending claims being examined in this application. Claims 1-5, 7-15, and 38 are rejected.

Claim 1 has been amended to even further clarify the claimed invention and to incorporate the subject matter of claim 14. Claim 1 has been amended to replace "a single-stranded polynucleotide comprising" with "a single-stranded polynucleotide consisting of", and to recite "a recombinant vector" wherein "component (I) comprises a polynucleotide sequence complementary to the polynucleotide sequence of component (III), wherein component (II) is a bond or a polynucleotide sequence of from 1 to 20 nucleotides in length." Support for the amendment to claim 1 may be found at page 5, 1st full paragraph, and page 6, lines 5-19 of the specification.

Claims 4, 5, and 7-8 have been amended to be consistent with claim 1. Claims 4, 5, and 7-8 have been amended to recite a "recombinant vector."

Claim 4 has been amended to recite "wherein the component (I) or (III) further comprises 1 or more U, T, G, C, or A nucleotides on at least one terminal, or has deleted, substituted, or added 1 or more U, T, G, C, or A nucleotides within said complementary sequence." Support for the amendment to claim 4 may be found at page 26, lines 15-24, and page 27, line 18 to page 28, line 20.

Claim 5 has been amended to recite that the promoter sequence is at one end and/or the terminator sequence is at the other end of the single-stranded polynucleotide sequence

Support for the amendment to claim 5 may be found at page 23, lines 18-21. The claim dependency of claim 5 was also changed

Claim 7 has been amended to change the claim dependency to claims 1 to 6, and to recite "wherein the single-stranded polynucleotide is obtained by chemical synthesis or gene recombination technology." Support for the amendment to claim 7 may be found at page 27, line 18 to page 28, line 20.

Claim 8 has been amended to recite "wherein component (II) is from 7 to 12 nucleotides in length." Support for the amendment to claim 8 may be found in the Examples.

Claim 9 has been amended to even further clarify the claimed invention, and to recite that the method for manufacturing the recombinant vector comprises "chemically synthesizing said vector or producing said vector by recombination gene technology. Support for the amendment to claim 9 may be found throughout the specification, for instance, at page 15, lines 9-18 and paragraph bridging pages 17-18.

Claim 10 has been amended to refer to a pharmaceutical composition. Support for the amendments to claims 10 and 11 may be found at page 36, line 6 to page 40, line 24.

Claim 18 has been amended to change the claim dependency to claim 1.

New claim 41 includes the limitations of claims 1 and 6. Support for new claim 41 may be found at least at page 23, line 26 to page 24, line 3.

New claim 42 includes the limitations of claims 1 and 12. Support for new claim 42 may be found at least at page 5, 1st full paragraph and page 11, 1st full paragraph.

No new matter is added.

Applicants note that the Examiner mistakenly excluded claims 17 and 18 on the form PTOL-326. However, on page 2 of the Office Action, the Examiner correctly included claims 17 and 18 in the claims of the Group I election made by Applicants, and

included the claims for examination on the merits on pages 3 and 6 of the Office Action.

Election/Restrictions

Applicants thank the Examiner for acknowledgement of Applicants' election with traverse of Group I (claims 1-15, 17, 18, 35 and 38) in the Response filed July 26, 2007.

Although the Examiner has made the Restriction Final, Applicants respectfully request that the method claims remain pending subject to rejoinder upon an indication of the allowability or allowance of any of the elected claims.

Response To Rejections Under 35 U.S.C. § 112 For Indefiniteness

Claims 1-5, 7-15 and 38 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action asserts that lines 6-9 of claim 1 is allegedly unclear as to what is meant by a target gene having "RNA suppression activity in relation to RNA having a sequence complementary to either component (I) or (III) or a partial sequence thereof."

The Office Action asserts that lines 3-7 of claim 38 is allegedly unclear because of the recitation "1 to 5 ribonucleotides continuing at 18-25 ribonucleotides complementary to the target gene, and component (I) comprises 18 to 25 ribonucleotides complementary to the 18 to 25 nucleotides complementary to the 18 to 25 ribonucleotides of component (III)."

Applicants submit that one of ordinary skill in the art would understand from reading the specification, that the presently claimed recombinant vector is a specific structure such that the range of components (I) and (III) for a target gene which is 15 to 30 or 18 to 25 nucleotides in length

sequences, and component (II) is a bond or a polynucleotide sequence of from 1 to 20 or 7 to 12 nucleotides in length.

Also, because methods for preparing a vector is widely known in the art, preparation of the vector of the present invention may be understood by one of ordinary skill in the art based on the disclosure of the specification and known techniques.

Claims 11-15 and 38 are canceled. Thus, the rejection is moot with regard to claims 11-15 and 38.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Response To Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-5, 7-15, 17, 18 and 38 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

The Office Action provides a detailed discussion of the rejection at pages 3-5 of the Office Action. For brevity, the discussion is not reiterated here. It appears the Office Action's position is that the claims allegedly encompass a broad genera of nucleic acids without adequately describing elements that appear to be essential to the claimed invention. The Office Action contends that the specification and claims do not indicate what distinguishing attributes are required or shared by the members of these broad genera of nucleic acids claimed.

The Office Action asserts that the claimed nucleic acids share no common, identifying structural attributes, and the specification provides no guidance to one of ordinary skill in the art. The Office Action asserts that the specification fails to teach or adequately describe a representative number of species in the various genera of nucleic acids claimed such that one of skill in the art would reasonably conclude that Applicants were not in possession of the claimed invention.

In response, Applicants submit that one of ordinary skill in the art would understand from reading the specification, that the presently claimed recombinant vector is fully described in the present specification, and that Applicants were in possession of the presently claimed invention at the time the invention was made.

Applicants note that the presently claimed recombinant vector produces an RNA structure, wherein a sequence with a length, e.g., 1-20 bases or 7-12 bases, forms a loop structure in cells or tissues so that the components (I) and (III) are complimentary to each other.

The presently recombinant vector is introduced into cells or tissues, to suppress activity of the RNA expressing a target gene (an RNAi effect). This effect involves using the presently claimed recombinant vector comprising an isolated or purified single-stranded polynucleotide sequence comprising continuous components (I) + (II) + (III) to directly suppress the RNA of a target gene, or using the presently claimed recombinant vector to indirectly affect RNA expressing a target gene.

One of ordinary skill in the art would further understand that a recombinant vector of the presently claimed invention can further comprise a promoter sequence located at both ends of a single-stranded polynucleotide sequence comprising a continuous components (I) + (II) + (III) so that the nucleotide sequence is inwardly expressed. Such a recombinant constituent enables effective RNA function suppression of a desired RNA function in cells or tissues. Such method for constructing the presently claimed recombinant vector and the use thereof, is a common technique known to those of ordinary skill in the art.

It is known to a person skilled in the art that the vector-inserted components (I) and (III) comprising DNA or RNA for a target gene varies depending on the use of the vector (for example, DNA or RNA to be inserted into a vector for gene

therapy). An example of the target gene for a recombinant vector of the present invention is described on page 36, lines 6 to 20 of the present specification.

Once either of the polynucleotide sequences for a target gene comprising component (I) or (III) is determined, a complementary sequence thereof is determined using a general method for determining an insert polynucleotide sequence for a gene that is known and generally used in the art of recombinant DNA techniques (e.g., sense DNA and the antisense DNA used in gene therapy). For instance, when a polynucleotide sequence comprising component (I) is determined, a person skilled in the art can easily determine and produce component (III) which is a complimentary sequence thereof. Also a person skilled in the art can prepare modifications as required in Claim 4.

Furthermore, page 20, line 7 to page 21, line 25 of the present specification discloses a method for determining the inserted polynucleotide sequence for a target gene comprising component (I) or (III). Page 29, line 7 to page 30, line 6 of the specification discloses a more concrete example of the method. According to such methods, the components can be determined and constructed.

The presently claimed recombinant vector relates to a novel recombinant vector comprising a novel component such as a polynucleotide containing continuous components (I), (II) and (III), a process for the production thereof, and a pharmaceutical composition containing the recombinant vector as an active agent. The presently claimed invention is sufficiently described in the present specification.

Further, the presently recombinant vector comprising a single-strand polynucleotide sequence has advantages over the conventional art in that the present invention, a single-stranded polynucleotide sequence provides more protection than a double-stranded molecule as a result of one-sided terminal

exposure (the 3' terminal side of the component (I) of the present invention), and increases the stability of the vectors in which a sequence for a target gene or a polynucleotide sequence of a target gene of the present invention has been introduced.

The sequence of a component (III), which contains a sequence complementary to the target gene sequence, and the sequence of a component (I), which is a sequence complementary to that of the component (III) can be selected and synthesized according to page 29, line 7 to page 30, line 6 of the specification.

For example, one of ordinary skill in the art would understand and be able to conduct an NCBI blast search based on the gene sequence information of the targeted gene, the AA(N19)TT sequence region, which is 50 to 100 bases downstream from the initiation codon of the coding region of the target gene, and which is comprised of about 50% G or C, is selected as the region complementary to part or all of the component (I). Alternatively, the component (III) region may be set up to be complementary by taking AA(N21) or CA to be the terminal site. For instance, if the base of the component (III) is determined to be a 21-oligonucleotide sequence in which two uracil bases are added to the 3' terminal of the 19-oligonucleotide sequence, then another base may be determined taking the sequence complementary to the 19-oligonucleotide sequence region of the component (III) as the sequence comprising the component (I). Then, once an oligonucleotide sequence comprising the RNA sequence of an optional 7 or 12 bases is determined to be the component (II), these oligonucleotides are combined, and after using a commercial automatic synthesizer to chemically synthesize, desalinate and purify single strand polynucleotide sequence comprising continuous components (I) + (II) + (III), the RNA for RNA transfection is dissolved in distilled water, a

mixed solution of buffer solution (100 mM potassium acetate, 30 mM HEPES-KOH adjusted to pH 7.4, 2 mM magnesium acetate) is prepared, and solutions of various dilution percentages are prepared using PBS and the buffer solutions.

For at least the reasons discussed above, a person skilled in the art would be able to make and use the presently claimed vector according to the guidance provided in the present specification.

Additionally, Applicants submit herewith a Rule 132 Declaration providing additional data to show that a skilled person in the art can make and use the claimed vector according to the method described in the specification without undue experimentation. The Declaration demonstrates that other target genes may be used in the presently claimed vector.

Claims 11-15, 17, and 38 have been canceled. Thus, the rejection with regard to claims 11-15, 17, and 38 is rendered moot.

Accordingly, reconsideration and withdrawal of the rejection under § 112, first paragraph is respectfully requested.

Response to Claim Rejections Under 35 U.S.C. § 102(b)

Claims 1-4, 7, 12-15, 17, 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tuschl et al (WO 2001/75164; "Tuschl").

The Office Action asserts that Tuschl teaches methods of manufacturing and using compositions comprising expression vectors encoding RNAi polynucleotides comprising three portions and having between 15-30 nucleotides, where two portions are self-complementary, comprising the target sequence of SEQ ID NO. 1, and wherein some bases in portions I or III are deleted, substituted or added, which polynucleotide comprises DNA and RNA.

In response, Applicants submit that Tuschl does not disclose the presently claimed recombinant vector for at least the following reasons.

As discussed in the present specification at page 27, line 18 to page 28, line 17, Tuschl is directed to use of a vector that is divided in two, in which a sequence for a target gene or a polynucleotide sequence for a target gene is inserted.

Also, with regard to Tuschl, it is necessary for oligo-RNAs transcribed from separate promoters to meet and associate by chance within a cell that has an extremely large space (a space of 10 to 13 fold of the size of the oligo-RNA), and it may be assumed that the function of the type that is divided into two is weak because the efficiency is extremely low.

In contrast, the presently claimed recombinant vector comprises an isolated or purified single-strand polynucleotide sequence comprising continuous components (I) + (II) + (III), wherein component (I) comprises a polynucleotide sequence complementary to the polynucleotide sequence of component (III), wherein component (II) is a bond or a polynucleotide sequence of from 1 to 20 nucleotides in length, and wherein component (III) is a polynucleotide sequence from 15 to 30 in length that has a polynucleotide sequence complementary to that of a target gene, wherein said target gene has an RNA function suppression activity in relation to RNA having a sequence which is complementary to either component (I) or (III) or a partial sequence thereof. Therefore, the production of the recombinant vector of the present invention is extremely significant considering that the sequences are inserted in the cell as a molecule having complementarity and are always in close proximity, and allow annealed strands that destroy RNA to be formed efficiently.

Furthermore, the structure of the present vector differs from the vectors disclosed in Tuschl. The RNA molecule

described in Tuschl consists of polynucleotide sequence obtained by adding 1 to 3 base(s) to N or C terminal of RNAi polynucleotide (see page 14, lines 20-30). Unlike the claimed component (II) of the present invention, the molecule of Tuschl does not form a loop structure. Instead, Tuschl forms a double stranded molecule, i.e., divided in two.

On the other hand, the recombinant vector of the present invention is constructed in such a way that component (I) and (III) make a single strand. Therefore, the presently claimed invention can provide more protection than a double stranded molecule because of the one-sided terminal exposure (the 3' terminal side of the component (I) of the present invention). Normally, exposed terminals are prone to attack by nuclease, and therefore being made into a single strand increases the stability of the vectors in which a sequence for a target gene or a polynucleotide sequence of a target gene of the present invention has been introduced.

Claims 11-15, 17, and 18 have been canceled. Thus, the rejection with regard to claims 11-15 and 17 is rendered moot.

Accordingly, reconsideration and withdrawal of the rejection under § 102(b) is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,
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